

Methodological Note

Allergopharma España

Preamble

These methodological notes are based on the methodological notes of the Merck Group for 2019. Allergopharma was a subsidiary of the Merck Group until March 31st, 2020. Allergopharma is part of the Dermapharm Group since April 1st, 2020. The transparency disclosures of Allergopharma for January 1st, 2020 to March 31st, 2020 are included in the transparency disclosures of the Merck Group.

This transparency disclosure covers the period from April 1st, 2020 to December 31st, 2020.

1. Introduction

This document summarizes the methodologies used in preparing Allergopharma España's disclosure according to the EFPIA HCP/HCO Disclosure Code and the Code of Practice for the Pharmaceutical Industry in Spain (Farmaindustria), identifying transfers of value, made directly or indirectly to or for the benefit of a Recipient.

Collaboration between pharmaceutical companies and healthcare professionals is necessary, as medicines are products of great scientific and technical complexity both in their production and administration. Doctors are involved as investigators, providing their experience and knowledge in the process of development of medicines, and companies foster educational activities to ensure healthcare professionals are up-to-date with regard to these treatments. This collaboration is amply regulated for both parties, ensuring that each patient receives the best possible treatment in accordance to his/her needs.

2. Definitions

Recipient

Any healthcare professional or healthcare organization, as applicable in each case, whose primary practice, principal professional address or place of incorporation is in Spain.

Healthcare organization (HCO)

Any legal body or entity (i) that is a medical or scientific organization, healthcare institution (of any legal status or organization), such as hospitals, clinics, foundations, universities and other academic entities, scientific societies (excluding patient organizations), or (ii) through which one or more healthcare professionals provide services.

Healthcare professional (HCP)

Any member of the medical, dental, pharmaceutical, nursing or podiatric profession, any other person legally considered as such, or any other person who, in exercising their profession, may perform or participate in the prescription, purchase, supply, dispensation or administration of medicinal products for human use.

Transfer of value (ToV)

Any direct or indirect transfers of value, whether in cash, in kind or otherwise, regardless of its purpose. Direct transfers of value are those made directly by a company for the benefit of a Recipient. Indirect transfers of value are those made by a third party (provider, agent, partner or affiliate – including foundations -) acting on behalf of a company for the benefit of a recipient when the company knows or can identify such recipient.

Transfers of value made as part of commercial transactions between companies and distributors, pharmacy offices and healthcare organizations are excluded from this concept.

Research and development

Activities related to the planning or conduct of (i) non-clinical studies (as defined by the OECD "Principles of Good Laboratory Practices"), (ii) clinical trials (as defined by Directive 2001/20/EC and considered in article 14.1 of the Code of Practice of the Pharmaceutical Industry) and (iii) post- authorization studies (considered in article 14.2 of the same Code).

3. Disclosure's scope

Products concerned

Prescription-only medicines.

Excluded transfers of value

- a. solely related to over-the-counter medicines;
- b. provision of materials and objects of informative or educational character;
- c. meals;
- d. samples;
- e. fees charged by logistics agencies assisting in organising travels and meetings;
- f. discounts, price reductions and other trading devices commonly used in the sale of medicinal products;
- g. healthcare packages provided by private entities purchased by Signatories for their employees;
- h. related to anonymous marketing research

Transfer of value date

- a. Date of transfer of value is the date of the paid invoice.
- b. In case of sponsorship of a healthcare professional to attend educational and scientific meetings organised by Allergopharma España or by a third party, the transfer of value date will be the starting date of the meeting or educational

activity.

Direct transfer of value

- a. Transfers of value are represented as the cost amount for Allergopharma España and not the recipient's revenue.
- b. Non-financial transfers of value are disclosed based on the financial valuation of the good or service.

Indirect transfer of value

- a. Transfers of value provided to healthcare organizations through a third party, e.g. through the PCO of a medical congress, are reported with the healthcare organization as recipient.
- b. Transfers of value to individual healthcare professionals executed through a third party are reported with the individual healthcare professional as recipient.

Transfer of value in case of partial attendance or cancellation

- a. In case of partial attendance or cancellation, or services not delivered, but value was transferred anyway e.g. according to contract clause, the transferred value is disclosed.
- b. If no value was transferred, the information on the transfer of value is not part of the report.

Cross-border activities

- a. Cases of cross-border transfers of value to healthcare professionals or healthcare organizations, falling in the scope of the Disclosure Code, are disclosed in accordance with the recipient's country of practice (healthcare professionals) or country of registration (healthcare organizations).
- b. If a healthcare professional or healthcare organization has several countries of practice / registration, the country where the recipient mainly carries out his/her practice discloses the transfers of value.

4. Disclosure of transfers of value made in 2017 and beyond

Individual disclosure of the transfers of value

On May 27th, 2016 a series of modifications to the Spanish Farmaindustria Code of Practice for the Pharmaceutical Industry came into force, with the aim of disclosing on an individual basis the transfers of value made to healthcare professionals starting on January 1st, 2017. The Spanish Data Protection Agency (SDPA) recognizes the legitimate interest of disclosure and, thus, the Healthcare Professionals' consent shall not be necessary for the disclosure, on an individual basis, of the Transfers of Value made to them; based on the report issued by the SDPA on April 2016 (available in the SDPA website). Due to the above, disclosure of transfers of value made in 2017 and beyond shall be made in an individual manner, provided the requirements sent in the Code are met.

Aggregate disclosure of the transfers of value

In reference to the Objection right, as set by the Code and as stated in SDPA Report, of 22 April (Annex I of the Code), if a Healthcare Professional exercising this right justifies to the company the existence of serious and legitimate grounds relating to a specific personal situation determining that, the reversal of the rule of balancing should apply, not prevailing the transparency legitimate interest that covers its publication, Allergopharma España shall exclude that Healthcare Professional data and disclose it, exceptionally, on an aggregate basis.

In the event of Allergopharma España receiving a request from an HCP objecting to the individual disclosure, the company will evaluate the possibility to put on hold the disclosure of the transfers of value to this HCP until the serious and legitimate reasons relating to a specific personal situation alleged by the HCP are analyzed. Following said analysis and after providing an answer to the HCP, data of this HCP will be published again in an individual or aggregated manner based on the conclusions reached regarding the serious and legitimate reasons.

Interactions excluded from the report

The report issued by the SDPA provides for certain measures to make an individual disclosure of the transfers of value, as indicated in the previous section, among others, to provide comprehensive information to the healthcare professional prior to the taking place of the interaction involving a transfer of value.

Compliance with applicable regulations on personal data protection

Allergopharma España commits to strictly complying with applicable regulations on personal data protection. As for those data subjects that are individuals, healthcare professionals, they can execute at all times their rights of access, rectification, erasure, restriction and objection to processing and the right to data portability by written request to the data protection officer at dataprivacy@allergopharma.com. In addition, the healthcare professional can also raise any questions to the competent data protection authority, as indicated in the contracts and agreements signed by each healthcare professional with Allergopharma España.

5. Specific considerations

Unique country local identifier

As required by EFPIA and Farmaindustria Codes of Practice, the compulsory data for the identification of a Recipient is:

- Full name,
- City of principal practice for a healthcare professional and city where registered for a healthcare organization,
- Unique Country Local Identifier, it being a partially visible DNI for a healthcare professional and a partially visible CIF for a healthcare organization.

Multiannual agreements and transfers of value in different calendar years

In the case of multiannual agreements or other agreements based on which the transfers of value were provided in different calendar years, the information included in the report pertains to those which were effectively paid to the recipient in a given calendar year / reporting period.

6. Categories of the transfers of value

Donations

A donation (monetary grant or benefit in kind) is an act of generosity through which a Company (donor) makes an amount of money, goods or services (donation in kind) freely available to a third party (donee), which accepts it. In all cases, the donor will not receive or request any compensation from the donee.

Allergopharma España performs two types of transfers of value within this category; donations for patient benefit and fundings to healthcare organizations for the execution of independent educational and scientific meetings.

Educational and scientific meetings

An educational or scientific meeting is a scientific-professional meeting, medical or promotional, consisting in a congress, conference, symposium, workshop, course, or any other type of similar activity organized by a healthcare organization or the pharmaceutical company.

Sponsorship agreements with healthcare organizations / third parties appointed by healthcare organizations to manage an Event:

Allergopharma España performs sponsorships consisting in the provision of financial or other support in the form of money, services, goods, or other items of value for a healthcare-related event or activity with a commercial, medical or scientific purpose, whether full or partial, related to the Allergopharma España business for which Allergopharma España expects to receive a material benefit in exchange for its support (e.g., a medical or scientific conference, a community-based activity that is healthcare-related, such as a fundraiser for a particular disease, or a community health fair). Sponsorships that are not directly related to educational activities and scientific-professional meetings, such as the sponsorship of a Healthcare Organization's website or a healthcare aimed mobile application, are also included in this category.

Registration fees:

Allergopharma España covers the cost of registration fees for healthcare organizations and healthcare professionals requesting support for their education through attendance to scientific and educational meetings. This support is based on objective criteria directly related to the purpose of the educational activity, such as their being renowned or their reputation amongst the scientific community, knowledge and expertise in the therapeutic area or topic of the educational program, potential to increase their knowledge or possible impact in the quality of patient care.

Travel & accommodation:

With regard to the third party activities above and company organized meetings, costs of accommodation and/or travel may be covered. Allergopharma España only

offers hospitality within the framework of a scientific meeting, in a reasonable manner, moderate and adjusted to its duration. No costs of accompanying persons or other invitees different from the healthcare professional are covered, nor any related to recreational or entertainment activities, nor is compensation offered to healthcare professionals for attending such educational activities.

Fees for service

Allergopharma España engages qualified healthcare professionals and healthcare organizations to provide services to the company so as to allow Allergopharma España to promote the improvement of clinical practice and patient care. Allergopharma España engages healthcare professionals and/or healthcare organizations as consultants, speakers or providers of other services exclusively when a legitimate need has been previously identified.

Fees:

Fees are in accordance with market value, depending on the nature of the service, role/responsibility assumed, professional category and time required. The selection of the professional is based on objective criteria directly related to the purpose of the engagement.

Related expenses agreed to in the fee for service or consultancy contract, including travel & accommodation:

Allergopharma España only offers hospitality and other expenses associated to the fee for service (such as the printing of materials necessary to carry out such service) in a reasonable, moderate and adjusted to the duration of the activity manner. The criteria set forth in the case of educational and scientific meetings also apply.

Research & Development

The amount in research and development includes activities related to the design and execution of preclinical studies, clinical studies and observational studies. This figure includes both transfers of value related to global studies – performed mainly by Allergopharma Headquarter in Germany, and those related to local studies covered by the Spanish entity. In the case of studies where nationality of healthcare organization recipients of the amounts cannot be determined, disclosure shall be made in the R&D section of the group Headquarters report (Allergopharma Germany). It also includes research support provided to Healthcare Organizations for the execution of research projects, whose adjudication is announced publicly. Finally, transfers of value to healthcare organizations for clinical research (clinical research organizations – CROs) are excluded from the total.

7. Disclosure Form

Date of publication

Disclosure will be made within the six months following the end of the reporting period, which in Spain corresponds to the natural year. The exact date of publication varies among EFPIA Countries and depends on legal stipulations.

Disclosure platform

Disclosure reports will be published on the international Allergopharma website (<https://www.allergopharma.com/our-business/taking-responsibilities/transparency.html>).

Disclosure language

Reports will be disclosed in Spanish.

8. Disclosure of financial data and calculation rules**Currency**

- a. Total value of the transfers of value is disclosed in local currency, Euro, after conversion from foreign currencies per the exchange rates adopted on the day of documenting the effective payments in the electronic system.
- b. Reference point of conversion is EUR.
- c. Transfers of value rates in foreign currency are converted into EUR at the exchange rate prevailing on the date of payment.

VAT included or excluded

Transfers of value are disclosed with VAT excluded.

Calculation rules

- a. Transfers of value effected in the reporting period are summed up according to the segmentation of the Farmaindustria disclosure template requirements.
- b. Only amounts of payments effected within April 1st to December 31st 2020 (reporting period) are considered for the calculation (see also note re ToV date and ToV in different calendar years).
- c. Calculation is executed with amounts of harmonized (same) currency (see also note to Currency).

9. Legal disclaimer

The document containing the information regarding Allergopharma España's disclosure includes, errors and omissions excepted, the data of which Allergopharma España is aware with regard to this object, having made its best efforts in its preparation, with the aim of ensuring the accuracy and completeness of the data collected.

Furthermore, no general habilitation to perform an additional treatment of the data of healthcare professionals is derived from the information disclosure for those accessing the website, such as their cross-matching with information published in the websites of other members of EFPIA and/or Farmaindustria.